IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Okada et al.

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DIVISIONAL OF:

Applicants:	Okada et al.	Group Art Unit:	1641
Application No.:	09/120, 192	Examiner:	Dao-Thuy L. Nguyen
Filed:	July 22, 1998		
Title:	IMMUNOASSAY METHOD AND IMMUNOASSAY KIT		

Assistant Commissioner for Patents
Washington, DC 20231

January 4, 2002

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the present application on the merits, please enter the following amendment to the specification and claims:

In the Specification:

At page 1, between the title "IMMUNOASSAY METHOD AND IMMUNOASSAY KIT" at line 2 and "TECHNICAL FIELD OF THE INVENTION" at line 3, please insert the following paragraph:

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CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional of Application Serial No. 09/120,192, filed on July 22, 1998, now U.S. Patent No. _____. --

In the Claims:

Please rewrite claim 1 as follows:

1. (Amended) An immunoassay method comprising:

bringing an immobilized phase comprising, at different positions on a water-absorbable base material, at least two different first immunity substances wherein said first immunity substances are specific for assay target substances contained in a test sample that are selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin, into contact with a test sample and a liquid containing second immunity substances, wherein each of said second immunity substances is labeled with colored latex particles and binds with said assay target substances, thereby to form assay target substance-labeled immunity substance complexes and to bind said complexes with respective first immunity substances at the immobilized phase; and

detecting said labeled immunity substance complex.

Please rewrite claim 3 as follows:

3. (Amended) The immunoassay method of claim 1, wherein the contact is made by flowing the test sample, so that it is absorbed from one end of the water-absorbable base material, thereby to bind the assay target substance with the first immunity substance, and then flowing the liquid to allow absorption thereof by the base material, thereby to bind said second immunity substance with the assay target substance.

Please rewrite claim 4 as follows:

4. (Amended) The immunoassay method of claim 1, wherein the contact is made by having the test sample absorbed halfway up to the immobilized phase, allowing the liquid to be absorbed from one end of the water-absorbable base material, thereby to form a complex of said second immunity substance and the assay target substance, and binding said complex with the first immunity substance at the immobilized phase.

Please rewrite claim 5 as follows:

5. (Amended) The immunoassay method of claim 1, wherein contact between the test sample and the second immunity substances is made by positioning a label phase partially up the immobilized phase by adding the liquid containing the second immunity substance partially up the immobilized phase and drying the liquid, the label phase comprising the second immunity substance in such manner that the second immunity substance can be released from the base material upon contact with water, allowing the test sample to be absorbed from one end of the water-absorbable base material, thereby to

form a complex of said second immunity substance and the assay target substance, and binding said complex with the first immunity substance at the immobilized phase.

Please rewrite claim 6 as follows:

6. (Amended) An immunoassay device comprising:

an immobilized phase comprising plural first immunity substances each specific for an assay target substance immobilized on a water-absorbable base material; and

a label phase comprising a labeled immunity substance comprising second immunity substances, said second immunity substances are labeled with colored latex particles which bind with one of said assay target substances in such a manner that the second immunity substance can be released from the base material upon contact with water, said immobilized phase comprising at least two different first immunity substances wherein said first immunity substances are specific for assay target substances selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin contained in a test sample, said first immunity substances being immobilized on different positions on the water-soluble base material.

Please rewrite claim 7 as follows:

7. (Amended) An immunoassay kit comprising:

an immobilized phase comprising, on a water-absorbable base material, plural immobilized first immunity substances each specific for an assay target substance; and

a liquid containing second immunity substances, each of said second immunity substances is labeled with colored latex particles and is specific for one of said assay target substances, said assay target substances being at least two kinds of assay target substances selected from the group consisting of verotoxin-producing *Escherichia coli*, verotoxin and human hemoglobin, wherein the kit is specific for assay target substances selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin contained in a test sample.

A marked-up version of the amended claims are attached hereto.

REMARKS

Applicants request that the present amendment be entered prior to examination on the merits.

Respectfully submitted,

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Marked-up Version of Amended Claims

1. (Amended) An immunoassay method comprising:

bringing an immobilized phase comprising, at different positions on a water-absorbable base material, at least two different first immunity substances [capable of specifically binding with] wherein said first immunity substances are specific for [at least two kinds of] assay target substances contained in a test sample that are selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin [contained in a test sample], into contact with a test sample and a liquid containing second [labeled] immunity substances, [each comprising a second immunity substance that] wherein each of said second immunity substances is labeled with colored latex particles and [capable of binding] binds with said assay target [substance] substances, thereby to form [an] assay target substance-labeled immunity substance [complex] complexes and to bind said [complex] complexes with respective first immunity substances at the immobilized phase; and

detecting said labeled immunity substance complex.

3. (Amended) The immunoassay method of claim 1, wherein the contact is made by flowing the test sample, so that it is absorbed from one end of the water-absorbable base material, thereby to bind the assay target substance with the first immunity substance, and then flowing the liquid to allow absorption thereof by the base material, thereby to bind said [labeled] second immunity substance with the assay target substance.

4. (Amended) The immunoassay method of claim 1, wherein the contact is made by having the test sample absorbed halfway up to the immobilized phase, allowing the liquid to be absorbed from one end of the water-absorbable base material, thereby to form a complex of said [labeled] second immunity substance and the assay target substance, and binding said complex with the first immunity substance at the immobilized phase.

5. (Amended) The immunoassay method of claim 1, wherein [the] contact between the test sample and the second immunity substances is made by [forming] positioning a label phase [at a position half way] partially up [to] the immobilized phase by adding the liquid containing the second immunity substance partially up the immobilized phase and drying the liquid, the label phase comprising the [labeled] second immunity substance in such manner that the [labeled] second immunity substance can be released from the base material upon contact with water, allowing the test sample to be absorbed from one end of the water-absorbable base material, thereby to form a complex of said [labeled] second immunity substance and the assay target substance, and binding said complex with the first immunity substance at the immobilized phase.

6. (Amended) An immunoassay device comprising:

an immobilized phase comprising plural first immunity substances each [capable of specifically binding with] specific for an assay target substance immobilized on a water-absorbable base material[,]; and

a label phase comprising a labeled immunity substance comprising [a] second immunity [substance] substances, said second immunity substances are [that is] labeled with colored latex particles [and capable of binding] which bind with one of said assay target [substance,] substances in such a manner that the [labeled] second immunity substance can be released from the base material upon contact with water, said immobilized phase comprising at least two different first immunity substances [capable of specifically binding with] wherein said first immunity substances are specific for [at least two kinds of] assay target substances selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin contained in a test sample, said first immunity substances being immobilized on different positions on the water-soluble base material.

7. (Amended) An immunoassay kit comprising:

an immobilized phase comprising, on a water-absorbable base material, plural immobilized first immunity substances each [capable of specifically binding with] specific for an assay target substance[,]; and

a liquid containing [labeled] second immunity substances, each of said second [each comprising a second] immunity [substance that] substances is labeled with colored latex particles and [capable of binding with] is specific for one of said assay target [substance] substances, said assay target [substance] substances being at least two kinds of assay target substances selected from the group consisting of verotoxin-producing *Escherichia coli*, verotoxin and human hemoglobin, wherein the kit is specific for assay

target substances selected from the group consisting of a combination of verotoxin-producing *Escherichia coli* and verotoxin, a combination of verotoxin and human hemoglobin, and a combination of verotoxin-producing *Escherichia coli* and human hemoglobin contained in a test sample.